IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
CENTRAL DIVISION AT WORCESTER

UNITED STATES OF AMERICA,

Plaintiff,

v.

DANIEL R. MAROLD, an individual d.b.a. CHILL6,

Defendant.

Civil Case No. _22-11773-DJC__

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Daniel R. Marold, an individual doing business as "Chill6," and Defendant having appeared and having consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest, without admitting or denying the allegations in the Complaint, and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C. § 332, and its inherent equitable authority.

2. The Complaint for Permanent Injunction states a cause of action against Defendant under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399i (the "Act").

3. The Complaint alleges Defendant violates the Act, 21 U.S.C. § 331(d), by introducing or delivering for introduction into interstate commerce a new drug, as defined

in 21 U.S.C. § 321(p), that is neither approved pursuant to 21 U.S.C. §§ 355(b) or 355(j) nor exempt from approval.

4. The Complaint alleges Defendant violates the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce a drug, as defined in 21 U.S.C. § 321(g), that is misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that its labeling fails to bear adequate directions for use.

5. Defendant violates the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce food that has become adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i), in that it contains an unsafe food additive.

6. Defendant represents to the Court that, with the exception of holding and shipping any article of food (including but not limited to dietary supplements and their components) and/or any article of drug (collectively referred to as "Product(s)" herein) for destruction pursuant to Paragraph 10, at the time of entry of this Decree, Defendant is not directly or indirectly engaged in manufacturing, preparing, processing, packing, receiving, labeling, holding, and/or distributing any Product. With the exception of any Product in Defendant's possession that is covered by Paragraph 10, if Defendant later intends to resume manufacturing, preparing, processing, packing, receiving, labeling, holding, and/or distributing any Product, Defendant must notify the United States Food and Drug Administration ("FDA") in writing at least ninety (90) calendar days in advance of resuming operations what type(s) of Products Defendant intends to manufacture, prepare, process, pack, receive, label, hold, and/or distribute and comply with the requirements of Paragraph 7 of this Decree. Defendant shall not resume operations until receiving written

notice from FDA, as required by Paragraph 7.F of this Decree, and then shall resume operations only to the extent authorized in the written notice from FDA.

7. Upon entry of this Decree, Defendant and each and all of his directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons or entities in active concert or participation with any of them (including "doing business as" entities) (collectively, "Associated Persons"), who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from directly or indirectly manufacturing, preparing, processing, packing, receiving, labeling, holding, and/or distributing any Product, including but not limited to, at or from any location(s), at or from which, now or in the future, Defendant directly or indirectly has responsibility over, authority for, or any other responsible relationship to, the manufacturing, preparing, processing, packing, receiving, labeling, holding, and/or distribution of any Product, or is directly or indirectly engaged in any aspect of such activities, whether or not Defendant has an ownership interest in the business ("Facility"), unless and until:

A. Defendant has in effect with respect to the Product an approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. §§ 355(b) or 355(j); or an effective investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i); or the following requirements are met:

(1) Defendant removes from Defendant's Product labels, labeling, promotional materials, websites or social media pages owned or controlled by or related to Defendant, including but not limited to https://www.chill6.com/, and any future website(s) or social media page(s) created or controlled by or related to Defendant, and in any other media over

which Defendant has control:

(a) all representations that the Product diagnoses, cures, mitigates, treats, or prevents disease, and all representations that otherwise cause his Product to be a drug within the meaning of the Act; and

(b) all references, direct or indirect, to other sources that contain representations that Defendant's Product diagnoses, cures, mitigates, treats, or prevents disease, and representations that otherwise cause Defendant's Product to be a drug within the meaning of the Act; and

(2) Defendant retains, at Defendant's expense, an independent person or persons (the "Labeling Expert") who is without any personal or financial ties (other than a retention agreement to satisfy the requirements of this provision) to Defendant (or his immediate family) or to Defendant's Associated Persons (or their immediate families), and who, by reason of background, training, education, or experience, is qualified to assess Defendant's compliance with the Act, to review the claims Defendant makes for his Product(s) on his Product(s) labels, labeling, promotional material, and any websites or social media pages owned or controlled by or related to Defendant, including but not limited to https://www.chill6.com/, and any future website(s) or social media page(s) created or controlled by or related to Defendant, and in any other media over which Defendant has control. Defendant shall notify FDA in writing of the identity and qualifications of the Labeling Expert within ten (10) calendar days of retaining such Labeling Expert. If Defendant replaces such expert, Defendant shall notify FDA in writing of any such replacement within ten (10) calendar days after such replacement. Any replacement expert shall be qualified as described herein; and

(3) The Labeling Expert certifies in writing simultaneously submitted to FDA and Defendant that, based on a comprehensive review:

(a) The Labeling Expert has inspected any location(s) at which Defendant directly or indirectly prepares, processes, manufactures, packs, repacks, receives, labels, holds, promotes, and/or distributes his Products; and

(b) The Labeling Expert has identified all of Defendant's Products and reviewed, for each Product, Defendant's representations on Product labels, labeling, promotional material, websites or social media pages owned or controlled by or related to Defendant, including but not limited to https://www.chill6.com/, any future website(s) or social medial page(s) created or controlled by or related to Defendant, and any other media over which Defendant has control; and

(c) The Labeling Expert has determined that Defendant has implemented procedures that are adequate to ensure that Defendant's claims do not cause any of his Products to be a drug within the meaning of 21 U.S.C. § 321(g) unless and until the Product is the subject of an approved new drug application or abbreviated new drug application, or is exempt from approval under an investigational new drug application, 21 U.S.C. §§ 355(a), (b), (i), and (j).

The Labeling Expert's written certification shall analyze whether Defendant is operating in compliance with this Decree, the Act, and applicable regulations. As part of this certification, Defendant shall ensure that the Labeling Expert includes a detailed and complete report of the results of the inspection(s) conducted under Paragraph 7.A(3)(a), including references to Product names and regulations addressed in the process of conducting the review. The certification shall also include copies of all materials reviewed other than FDA regulations. Defendant's Labeling Expert shall submit his/her certification to FDA at the address in Paragraph 18;

B. Defendant retains, at Defendant's expense, an independent person or persons (the "Food Expert") who is without any personal or financial ties (other than a retention agreement to satisfy the requirements of this provision) to Defendant (or his immediate family) or to Defendant's Associated Persons (or their immediate families), except that this person may be the same as the Labeling Expert, and who, by reason of background, training, education, or experience, is qualified to assess Defendant's compliance with the Act, to inspect the Facility and review manufacturing records, to review the claims Defendant makes for his Product on his Product labels, labeling, promotional material, and any websites or social media pages owned or controlled by or related to Defendant, including but not limited to https://www.chill6.com/, and any future website(s) or social media page(s) created or controlled by or related to Defendant, and in any other media or promotional/informational material over which Defendant has control to determine whether Defendant's methods, processes, and controls are adequate to ensure that the food (and ingredients thereof) that he prepares, processes, manufactures, packs, repacks, receives, labels, holds, promotes, and/or distributes are in compliance with this Decree, the Act, and applicable regulations;

(1) Defendant shall notify FDA in writing of the identity and qualifications of the Food Expert within ten (10) calendar days of retaining such Food Expert. If Defendant replaces such expert, Defendant shall notify FDA in writing of any such replacement within ten (10) calendar days after such replacement. Any replacement expert shall be qualified as described herein;

C. The Food Expert certifies in writing simultaneously submitted to FDA and Defendant that, based on a comprehensive review:

(1) The Food Expert has inspected any location(s) at which Defendant directly or indirectly prepares, processes, manufactures, packs, repacks, receives, labels, holds, promotes, and/or distributes his Products and has reviewed manufacturing records, to evaluate the claims Defendant makes for his Product on his Product labels, labeling, promotional material, and any websites or social media pages owned or controlled by or related to Defendant, including but not limited to https://www.chill6.com/, and any future website(s) or social media page(s) created or controlled by or related to Defendant, and in any other media or promotional/informational material over which Defendant has control; and

(2) The Food Expert has determined that Defendant's methods, processes, and controls are adequate to ensure that none of the food (and ingredients thereof) that he manufactures, processes, packs, repacks, receives, labels, holds, promotes, and/or distributes has become adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i) in that it contains any unsafe food additive, including but not limited to Phenibut HCl.

The Food Expert's written certification shall analyze whether Defendant is operating in compliance with this Decree, the Act, and applicable regulations. As part of this certification, Defendant shall ensure that the Food Expert includes a detailed and complete report of the results of the inspection(s) conducted under Paragraph 7.C(1), including references to Product names and regulations addressed in the process of conducting the review. The certification shall also include copies of all materials reviewed other than FDA regulations. Defendant's Food Expert shall submit his/her certification to FDA at the address in Paragraph 18;

D. Defendant destroys in accordance with the procedures provided in Paragraph 10 all Products in his possession, custody, or control. Nothing in this paragraph shall require Defendant to destroy any article of food or drug within his residence that is intended for

his personal use and/or consumption;

E. FDA representatives, without prior notice and when FDA deems necessary, inspect Defendant's Facilities to determine whether the requirements of this Decree have been met and whether Defendant is operating in conformity with this Decree, the Act, and applicable regulations; and

F. FDA notifies Defendant in writing that Defendant appears to be in compliance with the requirements set forth in Paragraphs 7.A-D. In no circumstance shall FDA's silence be construed as a substitute for written notification.

8. Upon receipt of written notification from FDA under Paragraph 7.F, Defendant and each and all of his directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(d) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, any new drug, as defined in 21 U.S.C. § 321(p), that is neither approved pursuant to 21 U.S.C. §§ 355(a) or 355(j) nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. Violates 21 U.S.C. U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, any drug that is misbranded within the meaning of 21 U.S.C. §§ 352(f)(1), in that its labeling fails to bear adequate directions for use;

C. Violates 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, any food to become adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i), in that it contains any unsafe food additive, including but not limited to Phenibut HCl; and

D. Any act that results in the failure to implement and continuously maintain the requirements of this Decree.

9. Upon resuming operations after having complied with Paragraphs 7.A-D and having received written notification from FDA under Paragraph 7.F of this Decree, Defendant shall retain an independent person or persons who meets the criteria described in Paragraphs 7.A(2) and 7.B and is qualified to assess Defendant's compliance, and who may be the same person(s) as the Labeling Expert(s) and/or the Food Expert(s) (the "Auditor"), to conduct audit inspections of Defendant's Facilities. Defendant shall notify FDA in writing of the identity and qualifications of the Auditor within ten (10) calendar days of retaining him/her. After Defendant receives written notification from FDA under Paragraph 7.F of this Decree, audit inspections under this paragraph shall commence no less frequently than once every six (6) months for the next five (5) years. The first audit shall occur not more than six (6) months after Defendant has received FDA's written notification that he appears to be in compliance with the Decree. Audit inspections shall evaluate, at a minimum, Defendant's compliance with the requirements of this Decree.

A. At the conclusion of each audit inspection described in this paragraph, Defendant shall direct the Auditor to certify in writing to FDA, based upon the Auditor's inspection and review, whether Defendant is complying with the requirements of this Decree, the Act, and applicable regulations and identifying and describing in detail any deviations from those requirements. The Auditor's written certification shall include the specific results of his/her

inspection and review, including references to Product names and regulations addressed in the process of conducting the review. requirements. Beginning with the second audit report, the Auditor shall also assess the adequacy of any corrective actions taken by Defendant to correct all previous audit report observations, if any, and include this information in the audit report. The audit report shall be delivered contemporaneously to Defendant and FDA, as specified in Paragraph 18, no later than fifteen (15) calendar days after the date each audit inspection is completed. In addition, Defendant shall maintain the audit reports in separate files at his Facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any observations indicating that Defendant is not in compliance with the requirements of this Decree, the Act, or applicable regulations, Defendant shall correct those observations within thirty (30) calendar days of receiving the report, unless FDA notifies Defendant in writing that a shorter period is necessary.

C. Immediately upon correction, Defendant shall submit documentation of corrective action to the Auditor. Within fifteen (15) calendar days of receiving such documentation, the Auditor shall review the corrective action taken by Defendant. Within five (5) calendar days of concluding that review, Defendant shall ensure that the Auditor reports to FDA in writing whether each of the audit report observations has been fully corrected and, if not, which observations remain uncorrected.

D. If audit reports identify deviations from this Decree, the Act, and/or applicable regulations, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew.

10. Within fifteen (15) calendar days after the entry of this Decree, Defendant, shall destroy all Products that are in Defendant's possession, custody, or control. Nothing in this

paragraph shall require Defendant to destroy any article of food or drug within his residence that is intended for his personal use and/or consumption, except that any Chill6 product intended for personal use must be marked "For personal use by Daniel R. Marold only. Not for sale or distribution." Defendant shall not dispose of any Products in a manner contrary to the provisions of the Act, any other federal law, or the laws of any State or Territory in which the Products are disposed.

11. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, investigation, analyses of Defendant's Product(s), a report or data prepared or submitted by Defendant, any expert, and/or the Auditor, or any other information, that Defendant has failed to comply with the provisions of this Decree, violated the Act and/or applicable regulations, and/or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, and/or applicable regulations, FDA may, as and when it deems necessary, notify Defendant, in writing, of the noncompliance and direct Defendant, in writing, to take one or more of the following actions:

A. Cease all preparing, processing, manufacturing, packing, repacking, receiving, labeling, holding, promoting, and/or distributing of any or all Products;

B. Recall specified Products received, labeled, held, and/or distributed by Defendant. Defendant shall initiate the recall(s) within twenty-four (24) hours of receiving notice from FDA that a recall is necessary. Defendant shall, under FDA's supervision, destroy all Products that are in Defendant's possession, custody, or control for which a recall was initiated. Defendant shall bear the costs of such recall(s), including the costs of destruction. Defendant shall be responsible for ensuring that the destruction is carried out

in a manner that complies with all applicable federal and state environmental laws, and any other applicable federal or state laws;

C. Destroy any Product(s) at Defendant's expense;

D. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

E. Submit additional reports or information to FDA;

F. Issue a safety alert; and/or

a. 87ASq any other corrective action(s) as FDA, reasonably deems necessary to bring Defendant into compliance with this Decree, the Act, and/or applicable regulations.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law.

12. Any cessation of operations or other action described above in Paragraph 11 shall be implemented immediately and fully by Defendant and shall continue until Defendant receives written notification from FDA that Defendant appears to be in compliance with the requirements of this Decree, the Act, and applicable regulations, and that Defendant may resume operations. In no circumstance shall FDA's silence be construed as a substitute for written notification.

13. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendant's operations and Facilities, collect samples, and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted prompt access to Defendant's operations and Facilities, including but not limited to all buildings, equipment, in-process and finished materials and Products, containers, labeling, and other

promotional material therein; to take photographs and make video recordings; to take samples, of finished and unfinished materials and Products, containers, labels, labeling, packaging, and other promotional materials; and to examine and copy all records relating to the receipt, manufacture, processing, packing, receiving, labeling, promoting, holding, and distribution of any and all of Defendant's Products in order to ensure continuing compliance with the terms of this Decree. Defendant and Associated Persons are prohibited from destroying, discarding, altering, transferring, or otherwise making unavailable any documents and records in any format, including but not limited to electronic format, or otherwise within the custody or control of Defendant or Associated Persons. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

14. Within fifteen (15) calendar days after any FDA request for Defendant's Product(s) labels, labeling, promotional material, and any websites or social media pages owned or controlled by or related to Defendant, including but not limited to https://www.chill6.com/, and any future website(s) or social media page(s) created or controlled by or related to Defendant, and any other media over which Defendant has control, Defendant shall submit a copy of the requested materials (in electronic format unless otherwise specified) to FDA at the address specified in Paragraph 18.

15. Within ten (10) calendar days after the entry of this Decree, Defendant shall: (1) provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of his Associated Persons, and (2) post the Decree on all websites and social media under Defendant's control. In the event that Defendant becomes associated, at any time after the entry of this Decree, with new Associated Persons, Defendant shall:

(a) within fifteen (15) calendar days of such association, provide a copy of this Decree to each such Associated Person by personal service or certified mail (restricted delivery, return receipt requested); and

(b) on a quarterly basis, notify FDA in writing when, how, and to whom the Decree was provided.

17. Defendant shall notify FDA in writing at least fifteen (15) calendar days before any change in, character, or name of his business, including incorporation, reorganization, relocation, bankruptcy, dissolution, or assignment, lease, or assignments, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendant shall provide a copy of this Decree to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendant shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to any such assignment or change in ownership.

18. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Decree shall be prominently marked "Consent Decree Correspondence – Chill6 – [Topic]" and shall be addressed to the Division Director, FDA Office of Human and Animal Food Operations-East (OHAFO-E), FDA -158-15 Liberty Avenue,
Suite 2029, Jamaica, NY and electronically to orahafeast1firmresponses@fda.hhs.gov, with the email subject "Consent Decree Correspondence – Chill6 – [Topic]", where [Topic] is a succinct title describing the correspondence.

19. If Defendant fails to substantially comply with any material provision of this Decree, the Act, and/or applicable regulations, after being notified by the FDA or its agents of any such material violation and being given ten (10) days to comply, including any time frame imposed by this Decree, then Defendant understands and agrees that the liquidated damages are not punitive

in nature and their imposition does not in any way limit the ability of the United States to seek, or the court to impose, civil, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

20. Defendant shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

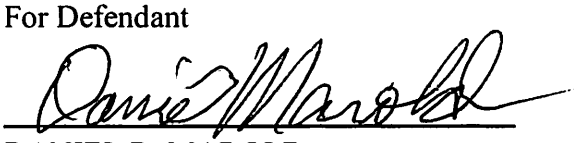
21. This Court retains jurisdiction of this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED, this _____ day of _____, 2022.

_____
UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree.

For Defendant



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